

REMARKS

Reconsideration is respectfully requested in light of the foregoing amendment and the remarks which follow.

Claims 1-3 are before the Examiner. Claim 1 has been amended to set forth the invention with more particularity. It is clearly drawn to a pharmaceutical or cosmetic formulation. As amended, the claim 1 specifies the pharmaceutical or cosmetic active ingredient is present in an effective amount for its intended use. The effect of "3.0 wt % of water-wettable contents" property of the hydrophobic highly dispersed silicon dioxide as resulting in a delayed release or time release of the active ingredient is more clearly set forth in the claim. It is noted in passing that destructuring of the pyrogenic silica gives rise to the increased "tamped density" values, which gives rise to improvements in tablet formation, e.g. hardness, and capsule formation, e.g. filling (flowability). Aerosil® 972 V (a densified hydrophobic fumed silica after treated with DDS (dimethyldichlorosilane) and based on a hydrophilic fumed silica with a surface area of 130 m²/g) is a more dense (destructured) version of Aerosil® 972 (a hydrophobic fumed silica aftertreated with DDS based on a hydrophilic fumed silica with a surface area of 130 m²/g). See Tables 2-8 and enclosed trade materials.

Clarification relative to the presence of the identification of the internet site appearing on page 9 of the specification at line 26. The article referred appears in an electronic "journal". The article was cited in the context of the presentation of background information. Does the Office wish to have the identification of the source or merely access information deleted? Clarification is respectfully requested. Applicants are ready to cancel the paragraph if that is what the Examiner wishes. A more complete background section is presented to the public if it remains intact. The application has been published. The identified site is in existence.

Claims 1-2 are rejected under 35 U.S.C. 102(b) as being anticipated by Shimizu et al (USPPA 2002/0102369) as evidenced by Scholz et al. (USP 6951642). Applicants respectfully traverse.

Shimizu et al. and Scholz et al. have been considered.

The rejection based on these references appears to have been prompted by the Examiners reading of the claims. The Examiner appears to have read the claim 1 as being direct to a composition merely containing a fumed silica like AEROSIL R972 V and an ingredient which is associated with a cosmetic. Applicants do not admit that this is a reasonable reading of the claim but see that the "suitable as" phrase could permit some latitude.

Claim 1 has been amended to clearly identify the composition as a pharmaceutical or a cosmetic formulation. Suitable cosmetic and pharmaceutical active ingredients are exemplified in the specification. It is also respectfully submitted the one of ordinary skill would understand what an "active ingredient" is under the circumstances and would also understand that an effective amount of the active ingredient would be present in amounts recognized as that to accomplish its use as a medicament.

For a reference to be anticipatory, it must teach each and every element required by the claims. Shimizu et al is directed to a lens with a protective coating Shimizu et al is not directed to a pharmaceutical composition. Shimizu et al is not directed to a cosmetic composition. Scholz et al. does not help in that regard, especially as to the claims as amended. The "suitable as" phrase is deleted.

Withdrawal of the rejection is respectfully requested.

Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shimizu et al (USPPA 2002/0102369) as evidenced by Schotz et al. (USP 6,951,642). Applicants respectfully traverse.

The deficiencies of the Shimizu et al. as evidenced by Schotz et al. combination is discussed above.

Schimizu et al. is not directed to a cosmetic formulation. Schimizu et al. is not directed to a pharmaceutical composition. The AEROSIL product present in Schimizu et al product

appears present as a "filler" in a coating composition. There are no pharmaceutical active ingredients or cosmetic active ingredients to optimize. The silica employed by Schimizu e al. is employed for a different function. It is not an aid to facilitate flowability. It is not an aid to impart hardness to a tablet. It is not seen how its optimization would lead to the claimed range.

Since a prima facie case has not been established, withdrawal of the rejection is respectfully requested.

Claims 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sebillote-Arnaud et al. (USPPA 200/0039976). Applicants respectfully traverse.

Sebillote-Arnaud et al. teach a cleansing composition composed of a foaming surfactant, a hydrophobic silica and a oxyalkylated compound. The compositions are foaming and rinsable cleaning compositions. The hydrophobic silicas taught include AEROSIL products. None of the AEROSIL products taught have a density that falls within the claimed tamped density range. It is noted that Sebillote-Arnaud et al. teach (paragraph [0021]) a preferred range of densities of 50-150 g/l for compacted silica. It is also noted that the exemplified AEROSIL products are not destructured or low structure products like AEROSIL R972 V. There is no mention of tablets or capsules, flowability of granular materials or hardness of tablets. It appears from paragraph [0104] that the addition of the hydrophobic silica and oxyethylated compound thicken the cleaning composition and lead to better rheological properties. These compounds have no impact on the cleaning properties of the foam.

The Examiner acknowledges that the Sebillote-Arnaud et al. reference does not teach AEROSIL R972 V but urges that its selection and use in Sebillote-Arnaud et al. composition would have been a obvious. (The statement of rejection does not include a reference showing the existence of AEROSIL R972 V. It is not clear that a more dense, low structure silica would be suited for use in the Sebillote-Arnaud et al. product. Reliance on applicants' specification for teachings is not proper under the circumstances here.)

This obviousness finding by the Examiner was not directed to the amended claims. The amended claims are clearly directed to a pharmaceutical or cosmetic formulation, where the active ingredient is present in an effective amount for the composition use as a medicament or cosmetic. As noted above AEROSIL R972 V is a distinct product from AEROSIL R972. The Tables in the specification show the use of the different AEROSIL R972 product results in different outcomes. These differences in outcomes would not be expected from the art of record. Also CP 1 and CP 2 establishes the significance for "water-wettable contents make up a max. of 3.0 wt %" limitation and also density. See Tables 7 and 8.

Accordingly, it is submitted that the teachings relied upon do not establish a proper prima facie case of obviousness. Further the results shown for AEROSIL R972 V would not be expected from the art of record. These results should be considered in the context propriety of the prima facie case. The results shown in the tables are believed to be commensurate in scope with the claims as amended.

Withdrawal of the rejection is respectfully requested.

Request for Interview

Applicants respectfully request either a telephonic or an in-person interview should there be any remaining issues.

CONCLUSION

All of the stated grounds of rejection have been properly traversed, accommodated, or rendered moot. Therefore, it is respectfully requested that the Examiner reconsider all presently outstanding rejections and that they be withdrawn. It is believed that a full and complete response has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

It is not believed that extensions of time are required, beyond those that may otherwise be provided for in accompanying documents. However, in the event that additional extensions of time are necessary to prevent abandonment of this application, then such extensions of time are hereby petitioned under 37 C.F.R. 1.136(a), and any fees required therefore are hereby authorized to be charged to **Deposit Account No. 02-4300, Attorney Docket No.: 032301.608 (formerly 39509.213934).**

Respectfully submitted,
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